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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/781,586 02/09/2001 Leonard S. Girsh 4403-9 D12 1293 23557 EXAMINER 7590 08/20/2004 SALIWANCHIK LLOYD & SALIWANCHIK SHERRER, CURTIS EDWARD A PROFESSIONAL ASSOCIATION ART UNIT PAPER NUMBER 2421 N.W. 41ST STREET SUITE A-1 1761 GAINESVILLE, FL 32606-6669

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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47			Application I	No.	Applicant(s)		
			09/781,586		GIRSH, LEONARI	D S.	
	Office Action Summary		Examiner		Art Unit		
			Curtis E. She		1761		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)⊠)⊠ Responsive to communication(s) filed on <u>03/04/04</u> .						
•							
3)							
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
 4) Claim(s) 96-132 is/are pending in the application. 4a) Of the above claim(s) 96-106,111-114,116-126,131 and 132 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 107-110, 115 and 127-130 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 							
Applicat	ion Papers						
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority	under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
Attachmer	ut(s) ce of References Cited (PTO-892)		4) 🔲 Interview Summary	/ (PTO-413)		
2) Notion Notion Notion Notion	ce of Draftsperson's Patent Drawing Review (P mation Disclosure Statement(s) (PTO-1449 or er No(s)/Mail Date			Paper No(s)/Mail D Notice of Informal I Other:	ate	O-152)	

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DETAILED ACTION

Election/Restrictions

Newly submitted claims 96-106, 111-114, 116-126 and 131-132 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are directed to products (previously withdrawn invention or species previously claimed in the collective.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims -106, 111-114, 116-126 and 131-132 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 107-110, 115, and 127-130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The new claims recite the use of super critical or critical liquid nitrogen and no specificational basis for this limitation was found.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 115 and 127-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 115 is indefinite because it is not clear where in the process "the milk" is assayed for allergen content.

Claim 128 is indefinite because the scope of the phrase "fine particle milk" is unknown.

Claims 127-130 are indefinite because the scope of the term "about" is unknown.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 107 and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitt (U.S. Pat. No.5,707,634)

Schmitt teaches the production of finely divided solid crystalline powders, including foods, such as powdered milk. (Col. 4, lines 20-27). The milk is dissolved in a

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suitable liquid carrier solvent is contacted with supercritical or liquefied gases such as carbon dioxide (anti-solvent). (Col. 4, lines 28- col. 6, line 24). Again, see *In re Best*.

Claims 107 and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis *et al.* (U.S. Pat. No. 4,848,094)("Davis").

Davis teaches the treatment of milk in Example 1, whereby liquid nitrogen is contacted with drops of milk. It is inherent that the patented process will obtain the claimed attributes of the final products. Again, see *In re Best*, above

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 108, 109 and 127-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis or Schmitt.

Davis and Schmitt teach that cited above, but does not specifically teach the use of defatted milk. The production of defatted milk, i.e., skim or fat free milk, as mentioned in the last office action is notoriously well known and therefore it would have been obvious to use a defatted milk in the process of Davis or Schmitt.

Applicants have added new claims directed to heating milk for a period of time and then evaporating said milk to produce evaporated milk. These limitations are notorious to the milk industry whereby they pasteurize milk to kill pathogens during its

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treatment. It would have been obvious to those of ordinary skill in the art to pasteurize the milk of Davis or Schmitt and produce powdered milk as this is notoriously well known in the milk industry.

Applicants' attention is invited to *In re Levin*, 84 U.S.P.Q. 232 and the cases cited therein, which are considered in point in the fact situation of the instant case, and wherein the Court stated on page 234 as follows:

This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients which produces a new, unexpected, and useful function. *In re Benjamin D. White*, 17 C.C.P.A (Patents) 956, 39 F.2d 974, 5 U.S.P.Q. 267; *In re Mason et al.*, 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 U.S.P.Q. 221.

Claim 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis or Schmitt in view of applicant's admissions (page 14 of specification).

Davis and Schmitt teach that cited above, but does not specifically teach the testing of the milk for allergens. Applicants admit (see page 14) that the testing of food products using RIA or ELISA is notoriously well known in the food art for its art recognized purpose, i.e., determining the level of allergens in food. It would have been obvious to those of ordinary skill in the art to test the milk of Davis or Schmitt for allergens, as taught by applicants, as it is notoriously well known to test foods in the claimed manner to determine the content of allergens.

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Response to Arguments

Applicant's arguments filed 03/03/04 have been fully considered but they are not persuasive.

Applicants argue that case law holds that even though each and every process step of a claimed invention is disclosed in the prior art, the fact that the claimed result is not disclosed indicates a lack of anticipation. The MPEP, § 2112, states the law that the Office follows regarding inherency, i.e., that something which is old does not become patentable upon the discovery of a new property. The prior art process steps are identical to those claimed and those of the instant specification and therefore, it is inherent that the claimed result is obtained, albeit unrecognized, in the prior art. See Ex parte *Novitski*, 26 USPQ2d 1389 (BPAI 1993). Therefore, the rejections are maintained.

With regard to the rejection based on obviousness, applicants again rely on the cited case law to overcome the anticipation of the claimed result. See response above. Applicants also assert that unexpected results are obtained in treating the defatted milk. To overcome the *prima facie* case of obviousness, the unexpected results must flow from that which is new in the art. With the instant rejection, what is new is not the use of claimed gas, but that the milk being treated is defatted. Applicants must show unexpected results are obtained by using defatted milk versus non-defatted milk.

The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis E. Sherrer, Esq. whose telephone number is 571-272-1406. The examiner can normally be reached on Tuesday-Friday, 8AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Curtis E. Sherrer, Esq. Primary Examiner Art Unit 1761